**July 16, 2016***

# Legislative Update

# for the Clinical Trials and Translational Research Advisory Committee

**Content current as of July 8, 2016*

## Activities of the 114th Congress-

## Second Session

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# *I. Budget and Appropriations*

## *FY 2017 Labor-HHS Appropriations Bills*

The Senate Appropriations Subcommittee for Labor, Health and Human Services, Education, and Related Agencies (L-HHS) considered its FY2017 L-HHS Appropriations Act on June 7, including a $2 billion increase for NIH for the second year in a row, and voted unanimously to advance the bill. The full Senate Appropriations Committee passed the bill out of committee with a vote of 29-1 (Sen. James Lankford, R-OK, was the only vote against the bill, citing concerns that the bill did not attempt to address recent Department of Labor overtime policies).

The House L-HHS Appropriations Subcommittee passed its bill out of the Subcommittee on July 6, and the Full Committee is expected to consider the bill on July 13. The House proposal includes a $1.25 billion increase for NIH, and Chairman Tom Cole emphasized his interest in seeing that increase grow in negotiations with the Senate, saying, "I understand my friends in the other body have provided a $2 billion increase for the NIH again this year. I want to be clear that I view the mark we set forth today as a floor, and not as a ceiling, for biomedical research funding, and I am hopeful that this number can increase as the process moves forward."

Both the House and Senate bills propose a number of targeted increases for specific NIH initiatives, as well as an across-the-board increase for all NIH Institutes and Centers. However, neither bill mentions or provides specific funding for the Vice President's Cancer Moonshot. This is not entirely surprising based on the appropriators' collective frustration with the structure of the budget proposal, as explained in detail below.

### *Highlights from the Senate Proposal*

The Senate bill proposes a $2 billion increase for NIH over FY2016, from $32.084 billion to $34.084 billion. This includes a proposed increase to NCI of $216 million over FY2016, from an appropriation of $5.21 billion in FY2016 to a proposed appropriation of $5.43 billion for FY2017.

The Senate FY2017 Labor-HHS bill would provide the following for specific NIH initiatives:

- A $400 million increase for Alzheimer's disease research (for a total of $1.39 B)
- A $100 million increase for the Precision Medicine Initiative Cohort (for a total of $230 for the PMI cohort); funding for PMI Oncology is kept flat, at $70 million, and is included in NCI's overall $5.43 billion proposed appropriation
- A $100 million increase for the BRAIN initiative (for a total of $250 million)
- A $50 increase to Combat Antibiotic Resistant Bacteria (for a total of $463 million)
- A $12.5 million increase for NIH's IDeA (Institutional Development Award) program (for a total of $333.4 million)
- $12.6 million for the Gabriella Miller Kids First Research Program within the NIH Common Fund (this is the same funding level as FY2016, as authorized in the Gabriella Miller Kids First Research Act)

### *Highlights from the House Proposal*

The House bill proposes a $1.25 B increase for NIH over FY2016, from $32.084 billion to $33.3 billion. This includes a proposed increase to NCI of $124.9 million over FY2015, from an appropriation of $5.21 billion in FY2016 to a proposed appropriation of $5.338 billion for FY2017.

The House FY2017 Labor-HHS draft bill would provide the following for specific NIH initiatives:

- A $350 million increase for Alzheimer's disease research (for a total of $1.26 B)
- The requested $100 million increase for the Precision Medicine Initiative Cohort (for a total of $230 for the PMI cohort); funding for PMI Oncology is kept flat, at $70 million, as proposed in the President's request
- A $45 million increase for the BRAIN initiative (for a total of $195 million)
- A $12.4 million increase for NIH's IDeA (Institutional Development Award) program (for a total of $333.3 million)
- $12.6 million for the Gabriella Miller Kids First Research Program within the NIH Common Fund (this is the same funding level as FY2016, as authorized in the Gabriella Miller Kids First Research Act)

***The FY2017 President's Budget and Appropriations Activity to Date***

The President's FY2017 Budget Request, released in February 2016, proposed an overall funding level for NIH of $33.1 billion, in a mix of discretionary and mandatory funds. Of note, that calculation included a $1 billion discretionary cut to NIH's base, balanced by an equivalent increase in mandatory funds. In addition, the budget included $680 million for the Moonshot supported through mandatory funding streams, which would require authorizing legislation (and offsets for the costs), a process that falls outside of the jurisdiction of the Appropriations Committees.

Appropriators, who spearheaded the $2 billion increase that NIH received for FY16, immediately voiced opposition to any cuts to discretionary funding for NIH, and many members of Congress expressed misgivings about a plan to increase mandatory spending. At the House L-HHS Subcommittee hearing on the NIH budget held on March 16, Chairman Rep. Tom Cole (R-OK) emphasized his position on the proposal in his opening remarks at the NIH hearing, noting, "I'm proud that last year this Congress was able to increase NIH funding by two billion dollars. And I'm confident that through these efforts, one day we'll find cures for diseases like cancer and Alzheimer's. I was therefore especially disappointed to see the proposed budget cut to the National Institute of Health this year by the administration. A proposal to divert one billion dollars of biomedical research funds to the mandatory side of the budget ledger and rely on new and possibly unlikely authorizations to continue the advances that we've made in increasing the research funding is disheartening. Frankly, I do not plan to let the one billion dollar cut stand." Similarly, House Appropriations Chairman Hal Rogers (R-KY) stated "We don't like mandatory spending. It's grown completely out of control...when I came to Congress, we appropriated two- thirds of federal spending. Now it's one-third. Entitlements were one-third and now they're two-thirds and growing. Unless we deal with it, we can't even pay the interest on the debt with discretionary funds. So that's why we are so dead set against mandatory."

Democratic Congresswoman Nita Lowey (NY), ranking Member of the full House Committee commented "[W]hile representing a net increase of $825 million, your budget will result in a one billion dollar cut in discretionary funding for NIH. And I assure you, that this Chair and Ranking Member and the big Chair and I will just not let that happen." She also voiced skepticism about the likelihood of success of the Administration's request, commenting "if you can get it [mandatory funding], good luck to you on that one."

Comments at the Senate L-HHS hearing for NIH echoed these concerns, as did language the Senate Committee included in the report that accompanied the L-HHS bill. The introduction to the NIH section of the report reads as follows:

*"The Committee rejects the administration's budget request to reduce discretionary funding for medical research at the NIH by $1,000,000,000. A continued commitment to NIH is essential to address our Nation's growing health concerns, spur medical innovation, sustain America's competitiveness, and reduce healthcare costs. After last year's historic increase of $2,000,000,000, the largest increase for the NIH in this bill in over a decade, the administration chose to take a step backwards by reducing discretionary funding for NIH. Instead of accepting this misguided budget request, the Committee increases funding by $2,000,000,000 above fiscal year 2016."*

While bipartisan support for NIH and for cancer research remains strong, Appropriators clearly disagree with the administration's approach to the FY2017 budget proposal for NIH.

***Next Steps***

Given the presidential election in November, we do not expect the L-HHS appropriations bills to progress to a floor vote and enactment. The most likely scenario is that Congress will pass a stopgap continuing resolution (CR) in late September to keep the government funded beyond the end of the fiscal year on September 30th, perhaps extending through December. After the elections, the "lame duck" period will provide Congress with an opportunity to work out an omnibus spending bill (combining all the pending appropriations bills into one vehicle) for passage before the end of the calendar year.

The alternatives to an omnibus are (1) a CR that would continue FY16 funding levels well into 2017 (likely into March, and a new Administration), or (2) a full year CR that would maintain the federal government at FY2016 levels for all of FY2017 (excluding emergency spending). Chairman Cole has indicated that in his view, a CR should be limited to the end of the calendar year, and that Congress should pass an omnibus appropriations bill before the close of the 114th Congress, not continue into the next Administration. Chairman Cole commented, "I think that's a big mistake and unfair to the next president, whoever that is. We should get our work done in a calendar year, and there's no reason why, particularly with an agreed-upon topline, that we can't." In recent weeks, members of the House Freedom Caucus have pushed for a floor vote on a six-month CR, running through March 2017, and making final funding negotiations the responsibility of a new Congress and new Administration. Staff to House Speaker Paul Ryan (R-WI) have indicated to the press that the Speaker is still focused on moving individual funding bills, implying that a floor vote on a six-month CR is unlikely.

## *II. Special Topics*

### Update: Senate HELP *Innovation for Healthier Americans* and House *21st Century Cures*

Prospects for passage of a comprehensive *Cures/Innovations* package are increasingly uncertain. The Senate HELP Committee has marked up a number of individual proposals and moved many out of committee in recent months. The HELP Committee's overall legislative package[1] is a complimentary

[1] The Senate package includes 19 bills that were passed out of the HELP Committee at hearings on February 9th, March 9th, and April 6th of 2016. Bills of particular relevance to NIH/NCI include the Promoting Biomedical Research and Public Health for Patients Act (summary on p.8), the FDA and NIH Workforce Authorities Modernization Act (summary on p.9), and the Advancing Precision Medicine Act (summary on p. 9); as well as the Advancing NIH Strategic Planning and Representation in Medical Research Act, the Advancing Targeted Therapies for Rare Diseases Act, and the Next Generation Researchers Act, which were highlighted in the March 9, 2016 CTAC Legislative Update.

effort to the House Energy and Commerce Committee's 21st Century Cures legislation, which the House passed nearly a year ago in July 2015.

Recent reporting and comments from leadership of both the Senate HELP committee and L-HHS Appropriations subcommittee indicate that negotiations in the Senate are ongoing regarding agreements on mandatory funding and the necessary offsets to pay for an "Innovation Fund" as described in the Senate proposal as a surge of mandatory funds for key initiatives. At the June 7 L-HHS subcommittee mark up of its FY 2017 bill, Sen. Lamar Alexander (R-TN), Chairman of the HELP Committee, called upon his colleagues for their help in the coming weeks, particularly for a "surge of funding for five projects identified by the NIH Director, including the Precision Medicine Initiative, the Cancer Moonshot, and the BRAIN initiative." Additionally, in his closing remarks, L-HHS Appropriations Subcommittee Chairman Roy Blunt (R-MO), emphasized the importance of the subcommittee's investment in medical research, turning to Sen. Alexander and commenting, "Your efforts in important surge areas are an important part of that, and hopefully we will see movement in the coming days."

The most recent coverage of the negotiations has not been encouraging. Earlier on in the process, champions of the legislation were hopeful that other Senate committees, including Finance, might be able to identify necessary offsets for the Innovation Fund, which has long been described as a deal-breaker for Democratic support. Identifying offsets in the Senate is particularly important since funding sources under the jurisdiction of the House Energy and Commerce Committee were used to support other legislation and are no longer available.

Senate Finance Committee Chairman Orrin Hatch (R-UT) recently commented, "I'd like to find the money for them but it's easier said than done. Unfortunately, when you talk to Democrats they want it all to come out of what Republicans like and when you talk to Republicans they want it all to come out of what Democrats like. … The cost of that is that you'll never have the 60 votes necessary."

## *III. Congressional Hearings, Briefings, and Visits*

Congressional Staff Visit to NCI (May 31): Staff to Congressmen Michael McCaul (R-TX) and Chris Van Hollen (D-MD), cochairs of the Congressional Childhood Cancer Caucus, visited NCI to meet with investigators in the Pediatric Oncology Branch in NCI's Center for Cancer Research (CCR), as well as extramural program leaders for NCI-supported pediatric oncology research, including childhood cancer survivorship research. Staff to Reps. Jackie Speier (D-CA) and Rodney Davis (R-IL), Sens. Jack reed (D-RI), Shelley Moore Capito (R-WV), and Brian Schatz (D-HI), also attended, as well as Majority staff for the House Energy and Commerce Committee, Subcommittee on Health.

Congressional Staff Visit to NCI (May 6): Staff to Rep. Steve Cohen (D-TN) visited NCI to meet with leadership of the Office of Cancer Nanotechnology Research, tour the radiation Oncology Branch in NCI's Center for Cancer Research (CCR), and visit with investigators at a cryo electron microscopy (cryo-EM) facility within CCR's High Resolution Electron Microscopy program.

Congressional Visit to NIH (April 12): Reps. Bob Dold (R-IL), Katherine Clark (D-MA), David Valadao (R-CA), Joe Kennedy (D-MA), and Susan Brooks (R-IN) visited NIH on April 12. They met with NIH Director Dr. Francis Collins and other NIH Institute and Center (IC) Directors, and toured Dr. Christian Hinrichs' lab in the NCI Center for Cancer Research's (CCR) Experimental Transplantation and Immunology Branch. They also met with one of Dr. Hinrichs' patients. Dr. Bill Dahut, CCR Clinical Director, welcomed

the group and joined them for the NCI portion of their visit. The members of Congress also toured facilities of other NIH ICs.

Senate L-HHS Appropriations Subcommittee NIH Budget Hearing (April 7): Dr. Doug Lowy, Acting Director, NCI, joined Dr. Francis Collins, Director, NIH, and other Institute and Center Directors at the NIH Budget Hearing before the Senate L-HHS Appropriations Subcommittee. Dr. Lowy fielded questions from Sen. Roy Blunt (R-MO), Chairman of the Subcommittee, about predictive oncology as it relates to identifying the most effective and necessary treatments for patients, and from Sen. Thad Cochran (R-MS), Chairman of the full committee, regarding recent breakthroughs as a result of investments funded through the appropriations process. In his response, Dr. Lowy mentioned the progression of immunotherapy research and the potential of the National Cancer Moonshot Initiative. The NIH and IC Directors were also given the opportunity to make any additional comments at the end of the hearing. Dr. Lowy mentioned the NEJM article that he and Dr. Collins wrote about the National Cancer Moonshot and highlighted the opportunities for cancer research to benefit patients and accelerate progress, from basic science through implementation.

Senate Clerks Visit to NIH (March 31): Laura Friedel, Clerk, and Alexander Keenan, Minority Clerk, Senate Appropriations Subcommittee on Labor, HHS, Education, and Related Agencies, came to NIH and were briefed on specific initiatives and programs of interest to them in advance of the Subcommittee's April 7 hearing on the FY2017 proposed budget. Drs. Doug Lowy and Dinah Singer met with the Clerks to discuss the National Cancer Moonshot and the Precision Medicine Initiatives.

Representative Comstock Visit to NIH (March 31): Representative Barbara Comstock (R-VA-10) visited NIH and met with NIH leadership. She toured labs in the Clinical Center, including NIDDK's Metabolic Clinical Research Unit and NCI's Women's Malignancies Branch. From NCI, Drs. Elise Kohn and Jung-min Lee, as well as Research Nurse Nicole Houston participated.

House L-HHS Appropriations Subcommittee NIH Budget Hearing (March 16): Dr. Doug Lowy, Acting Director, NCI, joined Dr. Francis Collins, Director, NIH, and other Institute and Center Directors at the NIH Budget Hearing before the House L-HHS Appropriations Subcommittee. Dr. Lowy fielded questions from Rep. Nita Lowey (D-NY), Ranking Member of the full committee, about goals and areas of focus within the National Cancer Moonshot Initiative, from Rep. Charlie Dent (R-PA) regarding colorectal cancer research and screening, and from Rep. Mike Simpson (R-ID) focusing on collaboration with the Department of Energy within the context of the National Cancer Moonshot Initiative.

Dr. John Schiller Spoke at Prevent Cancer Foundation Briefing (March 14): Dr. John Schiller, Deputy Chief of the Laboratory of Cellular Oncology, NCI Center for Cancer Research, will spoke on a panel at a congressional briefing on March 14 organized by the Prevent Cancer Foundation. The briefing focused on virally-induced cancers, and Dr. Schiller spoke about his research focusing on the link between HPV and cervical and other cancers. Other panelists include: Dr. Erich Sturgis, MD Anderson Cancer Center; Dr. Anna Giuliano, Moffitt Cancer Center; Dr. Rohit Satoskar, MedStar Georgetown University Hospital; and Ms. Kim Jappell, Patient Advocate. Congresswoman Debbie Dingell (D-MI-12) sponsored the briefing and made opening remarks.

## *IV. Legislation of Interest*

The following bills and resolutions were selected for inclusion in this update due to anticipated interest among the CTAC membership. More detailed information about these bills and others are available on our website: http://cancer.gov/about-nci/legislative/current-congress

**Recent Legislative Activity and Public Laws**

DoD Medical Research Provisions in FY 2017 National Defense Authorization Act (NDAA, S. 2943)

- The FY2017 NDAA authorizes appropriations and provides policy directives for the Department of Defense (DoD), military construction, and defense activities carried out by the Department of Energy. The bill was introduced by Chairman of the Senate Armed Services Committee, Sen. John McCain (R-AZ).
- Sen. McCain included provisions within the FY 2017 bill that aimed to restrict the scope of research supported through Department of Defense medical research programs, including cancer research efforts within the Congressionally Directed Medical Research Program (CDMRP). The provisions would have directed DoD to limit medical research efforts to those that aim to provide direct benefit to members of the Armed Services, and not veterans and military families; and would have imposed additional review and audit requirements for each award, contract, or cooperative agreement supported by the CDMRP.
- Senators Richard Durbin (D-IL) and Lisa Murkowski (R-AK) offered an amendment to the bill on June 7 to strike these provisions. The Senate voted 66-32 in favor of the Durbin/Murkowski amendment, removing these provisions from the NDAA bill.

Cancer Clusters Provisions - Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576; **P.L. 114-182**)

- H.R. 2576 aims to update and reauthorize the Toxic Substances Control Act of 1976. Provisions within the bill direct the Department of Health and Human Services to develop criteria for designating potential "cancer clusters," develop guidelines for investigating such clusters, and investigate such clusters.
- Currently, the Centers for Disease Control and Prevention, in partnership with the Council of State and Territorial Epidemiologists, provides guidelines for investigating suspected cancer clusters. Local or state health departments, along with cancer registries, currently respond to cancer cluster questions and have the most current local data. If needed, states request technical advice from CDC, its Agency for Toxic Substances and Disease Registry, and the Environmental Protection Agency.
- The House passed the bill in June 2015, and the Senate passed the bill in December 2015. The House approved an amended bill in May 2016, and worked to resolve differences with the Senate in early June. The Senate passed an amended version of the bill on 6/7/2016. **The President signed the bill into law on 6/22/2016 (P.L. 114-182).**

Breast Cancer Commemorative Coin Act (H.R. 2722/S.2185; **P.L. 114-148**)

- The bill aims to establish a Breast Cancer Awareness Commemorative Coin by requiring the Secretary of the Treasury to mint up to 50,000 $5 gold coins (to be sold for $35 per coin), up to 400,000 $1 silver coins (to be sold for $10 per coin), and up to 750,000 half-dollar coins (to be sold for $5 per coin) in 2018. Once the cost of design and issuance of the coins is covered, the surcharge would be paid to the Breast Cancer Research Foundation to further research funded by the organization.

- Rep. Carolyn Maloney (D-NY) introduced H.R. 2722 on 6/10/2015. The bill was referred to the Committees on Financial Services; and the Budget. S.2722 was introduced by Sen. Heidi Heitkamp (D-ND) and referred to the Committee on Banking, Housing, and Urban Affairs on 10/20/15.
- The House passed H.R. 2722 on 7/15/2015 after it was amended to remove Susan G. Komen as a co-recipient after a number of Republican Members of the House objected to the organization's support for breast cancer screening services provided by Planned Parenthood. The Senate passed the bill on 4/19/2016. **The President signed the bill into law on 4/29/2016 (P.L. 114-148).**

## Selected New Bills in the 114th Congress

Women and Lung Cancer Research Preventive Services Act of 2016 (H.R. 5263/S. 2941)

- The bill would require the Secretary of HHS, along with the Secretary of Defense and the Secretary of Veterans Affairs, to conduct and interagency study to evaluate the status of and make recommendations for increased research on women and lung cancer, access to lung cancer preventive services, and strategic public awareness and education campaigns on lung cancer.
- The bill also calls for a report to Congress, including a review of current and previous research related to women and lung cancer across the Federal Government, recommendations for a collaborative research program, and recommendations for the development of a national public education and awareness campaign.
- H.R. 5263 was introduced by Rep. Richard Nolan (D-MN) on 5/17/2016 and was referred to the Energy and Commerce Committee. S. 2941 was introduced by Sen. Kelly Ayotte (R-NH) on 5/17/2016 and was referred to the HELP Committee.

Breast Cancer Patient Protection Act of 2016 (H.R. 5195)

- This bill would require health plans to provide coverage for a minimum hospital stay for mastectomies, lumpectomies, and lymph node dissection for the treatment of breast cancer, as well as coverage for secondary consultations.
- H.R. 5195 was introduced by Rep. Rosa DeLauro (D-CT) on 5/11/2016 and was referred to the Energy and Commerce, Ways and Means, and Education and the Workforce Committees.

Reports Reduction Act of 2016 (S. 2875)

- This bill would remove the requirements for each of the following reports currently required to be submitted by the NIH: Annual Report on Pediatric Research Initiative, Biennial Report on Organ Donation, Biennial Report on Organ Transplantation, Report on Breast and Cervical Cancer Program, Repot of Trans-NIH Research, Annual Report on Living Organ Donation, and Report on Centers of Excellence.
- S. 2875 was introduced by Sen. Mark Warner (D-VA) on 4/28/2016 and was referred to the Committee on Homeland Security and Governmental Affairs.

Promoting Inclusion of Minorities in Clinical Research (S. 2745)

- This bill will require the NIH Director to develop, submit, and post on the website an NIH Strategic Plan to provide direction on biomedical research investments and facilitate coordination between ICs. ICs will also be required to prepare regular strategic plans, but specific requirements are not provided.
- The NIH Director would be required to collect, and make available on its website, data from each IC on study populations which specify the inclusion of women, minority groups, relevant age categories, as well as other demographic variables. In addition, the NIH director is directed to foster

collaboration between ICs to allow for increased subjects to be studied and the utilization of diverse study populations. This bill also directs the NIH Director to encourage efforts to improve research related to the health of sexual and gender minority populations.

- The bill redesignates "interagency coordination" as "Intra-NIH Coordination" to facilitate partnerships between ICs to achieve the goals of the NIH that are related to minority health and health disparities.
- The NIH Director would be required to convene a working group, within one year of the date of enactment, to develop and issue recommendations for a formal policy to enhance rigor and reproducibility of scientific research funded by NIH, and would require a report to Congress regarding implementation of the recommendations.
- Among other provisions, the bill also directs the NIH Director to develop policies for projects of basic research to assess relevant biological variables includes sex and how differences between male and female cells, tissues, or animals may be examined and analyzed.
- This bill was introduced by Sen. Susan Collins (R-ME) on 4/5/2016 and was referred to the HELP Committee. S. 2745 was reported out of committee on 4/18/2016.

<u>Genetic Research Privacy Protection Act (S. 2744)</u>

- This bill will require the Secretary to issue a Certificate of Confidentiality to researchers who apply for federal funding (regardless of whether the research receives funding) to conduct research in which identifiable, sensitive information is collected.
- Researchers that receive a Certificate of Confidentiality will be required to protect the privacy of those individuals who participate in their research.
- Exceptions to the disclosure of this information include instances when it may be necessary for medical treatment of the individual to whom the information pertains, when an individual provides consent to disclose of the information about himself or herself, and for use in other scientific research that is compliant with Federal human subjects protection regulations.
- This bill does not limit the access of research participants to information collected about them during their research participation. The bill also exempts from disclosure under FOIA biomedical information about an individual that is gathered or used during research.
- This bill was introduced by Sens. Elizabeth Warren (D-MA) and Mike Enzi (R-WY) on 4/5/2016 and was referred to the HELP Committee. The bill was included as an amendment to S. 2713, the Advancing Precision Medicine Act, on 4/6/2016.

<u>Promoting Biomedical Research and Public Health for Patients Act (S. 2742)</u>

- This bill directs NIH to prepare a triennial rather than a biennial report and includes provisions that would roll Trans-NIH Research Reporting into the Triennial report. The report must include a description of intra-NIH activities, including the percentage of funds made available by each IC for collaborative research and recommendations for promoting coordination of information among ICs. In addition, the bill specifies that relevant age categories must be included as part of the demographic variables for study participants.
- This bill requires the Secretary to review and revise policies related to the disclosure of financial conflicts of interest to harmonize and reduce the administrative burden on researchers. In addition, the NIH Director will be required to implement measures to reduce the administrative burdens related to monitoring subrecipients of grants by primary awardees; and to review and revise applicable policies for the care and use of laboratory animals to reduce administrative burden on investigators.

- The bill requires the OMB Director to establish a Research Advisory Board to provide information on the effects of regulations related to Federal Research requirements and make recommendations to harmonize these regulations across research agencies.
- This bill would allow NIH contractors to collect and retain payments from the sale of research substances, and to forward those payments to the Secretary by crediting the appropriations accounts that incurred the costs to make available the research products involved.
- This bill would allow the NIH Director to provide the option of clinical trial information for an applicable device clinical trial to be publicly posted prior to the date of clearance or approval.
- The NIH Director, in collaboration with the FDA Commissioner, would be required to submit reports regarding compliance under the Expanded Clinical Trial Registry Data Bank.
- The bill also recognizes that the NCI Director is appointed by the President and establishes 5-year terms for all other IC Directors, which are appointed by the HHS Secretary, through the NIH Director. For these IC Directors, there would be no limit to the number of terms they can serve.
- This bill was introduced by Sen. Lamar Alexander (R-TN) on 4/4/2016 and was referred to the HELP Committee. S. 2742 was reported out of committee on 4/18/2016.

<u>Advancing Precision Medicine Act of 2016 (S. 2713)</u>

- This bill encourages the Secretary to establish and carry out the Precision Medicine Initiative to augment efforts to address disease prevention, diagnosis, and treatment.
- In addition, the bill authorizes the Secretary to coordinate with the Secretary of Energy, private industry, and others; to develop and utilize public-private partnerships; and to leverage existing data sources.
- The Secretary would also be required to ensure the collaboration of the NIH, the FDA, and the Office of the National Coordinator for Health Information Technology; to comply with existing human subjects protection laws and regulations; to implement policies for appropriate secure data sharing; and to ensure diversity of participants.
- This bill allows the Secretary to exempt from disclosure under FOIA biomedical information about an individual that is gathered or used during biomedical research if it could be used to identify the individual.
- This bill authorizes the NIH Director to require recipients of NIH grants or cooperative agreements to share scientific data generated from the awards in a manner that is consistent with all applicable laws and regulations.
- In addition, this bill would allow the NIH Director to approve requests from ICs to use Other Transactions Authority to conduct or support high-impact, cutting-edge research. For each year the authority is used, ICs would be required to submit a report regarding the research activities supported by Other Transactions Authority.
- S. 2713 was introduced by Sen. Lamar Alexander (R-TN) on 3/17/2016 and was referred to the HELP Committee. The bill was reported out of committee on 4/18/2016.

<u>FDA and NIH Workforce Authorities Modernization Act (S. 2700)</u>

- The goal of this bill is to update the authorizing provisions relating to the FDA and NIH workforces.
- For NIH, this bill expands the Senior Biomedical Research Service appointment authority by increasing the maximum number of appointments from 500 to 2,000 and raising the salary cap to $400,000 (equal to the President's salary).
- The bill also exempts scientific meetings from conference reporting requirements and restrictions and exempts NIH research from the Paperwork Reduction Act.
- The bill was introduced on 3/17/2016 by Sens. Lamar Alexander (R-TN) and Patty Murray (D-WA) and was referred to the HELP Committee. S. 2700 was reported out of committee on 4/18/2016.

## Selected Recent Resolutions (114th Congress)

*This section highlights resolutions introduced to raise awareness about specific diseases or issues. It is important to note that resolutions are different than bills, in that they are used to express the sentiment of one chamber (House or Senate) on an issue. As such, resolutions do no not require concurrence of the other chamber or approval by the president, and they do not have the force of law.*

**Passed**

Designating September 2016 as "National Prostate Cancer Awareness Month" (S. Res. 517)

- This resolution designates September 2016 as National Prostate Cancer Awareness Month and calls for steps to raise awareness about prostate cancer screening and treatment; to support research to improve screening and treatment; and to improve access and the quality of health care services for detecting and treating prostate cancer.
- The bill was introduced by Sen. Jeff Sessions (R-AL) on 6/29/2016 and was agreed to by Unanimous Consent.

Designation of May 2016 as National Cancer Research Month (S. Res. 459)

- A resolution supporting the designation May 2016 as "National Cancer Research Month".
- The resolution recognizes the importance of cancer research and supports efforts to establish cancer research as a priority.
- S. Res. 459 was introduced by Sen. Dianne Feinstein (D-CA) on 5/9/2016, and the resolution was agreed to by Unanimous Consent on 5/25/2016.

Designation of March 2016 as National Colorectal Cancer Awareness Month (S. Res. 395)

- This resolution supports the designation of March 2016 as National Colorectal Cancer Awareness Month and encourages appropriate awareness and educational activities throughout the month.
- The resolution was introduced by Sen. Michael Enzi (R-WY) on 3/9/2016 and was agreed to by Unanimous Consent.

National Asbestos Awareness Week (S. Res. 376)

- The resolution designates the first week of April 2016 as National Asbestos Awareness Week, and recognizes that asbestos fibers can cause cancer such as mesothelioma.
- S. Res. 376 was introduced by Sen. Edward Markey (D-MA) on 2/25/2016, and the resolution was agreed to in the Senate on 3/9/2016.

Designation of March 6, 2016 as the first annual World Lymphedema Day (S. Res. 389)

- This resolution supports the designation of March 6, 2016 as the first annual World Lymphedema Day and recognizes advocates and healthcare providers that help those battling the condition.
- The resolution was introduced by Sen. Charles Schumer (D-NY) on 3/3/2016 and was passed by the Senate by voice vote.

**Introduced**

Designating September 2016 as "National Ovarian Cancer Awareness Month" (H. Res. 811)

- This resolution designates September 2016 as National Ovarian Cancer Awareness Month to increase public awareness for the disease.
- The bill was introduced by Rep. Rosa DeLauro (D-CT) on 7/7/2016 and was referred to the Committee on Oversight and Government Reform.

Designating September 2016 as "National Ovarian Cancer Awareness Month" (S. Res. 521)

- This resolution designates September 2016 as National Ovarian Cancer Awareness Month to increase public awareness for the disease.
- The bill was introduced by Sen. Kelly Ayotte (R-NH) on 7/7/2016 and was referred to the Judiciary Committee.

Designation of May 2016 as National Cancer Research Month (H. Res. 717)

- A resolution supporting the designation May 2016 as "National Cancer Research Month".
- The resolution recognizes the importance of cancer research and supports efforts to establish cancer research as a priority.
- H. Res. 717 was introduced by Rep. Kevin Yoder (R-KS) on 4/29/2016 and was referred to the Energy and Commerce Committee.

Designation of June 2016 as National Men's Cancer Awareness Month (H. Res. 705)

- The resolution expressed support for the designation of June 2016 as National Men's Cancer Awareness Month.
- H. Res. 705 was introduced by Rep. Alcee Hastings (D-FL) on 4/26/2016 and was referred to the Committee on Energy and Commerce.